JAN - 5 2012

K111717

510K summary

Company Name: Electro-Cap International, Inc.
1011 West Lexington Road
P.O. Box 87
Eaton, OH 45320

Contact: Amy Swallows
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Summary Date: June 15, 2011 (Revised December 30, 2011)

Trade Name: Electro-Gel

Common Name: Electrode Gel

Classification Name: Media, Electroconductive

Regulation Number: 21 CFR 882.1275

Product Code: GYB

Predicate Device(s):

510(k) Number: K780045
Manufacture: Electro-Cap International, Inc.
Trade Name: Electro-Gel

510(k) Number: K883149
Manufacture: Weaver and Company
Trade Name: TEN20 Conductive Paste

510(k) Number: K003924
Manufacture: Mavidon
Trade Name: Mavidon Electrode Jelly

510(k) Number: K033052
Manufacture: Compumedics USA, Ltd.
Trade Name: QuikGel

1.0 Description of Device

Electro-Gel is the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment. Electro-Gel is for use with external electrodes only.

Electro-Gel is an off white color, water-miscible conductive gel consisting of Sodium Chloride as the conductor combined with thickening agents, emulsifiers, humectants and preservatives all in an aqueous solvent.
The formula is as follows:

Water	Potassium Bitartrate
Aragum T-1998	Sodium Chloride
Methylparaben	Propylparaben
Glycerin	

The pH range is 4.5 to 6.0 pH, Viscosity range is 575 to 615 cp. and Impedance 0.5K/Ohms or less.
Direct contact with the Electro-Gel should not exceed 8 hours in any single recording session.
The Electro-Gel is available in the following jar sizes: 16 ounce, 32 ounce and 128 ounce. Shelf life is 1 year if stored properly, i.e. kept with containers tightly closed and at room temperature.

2.0 Intended Use of Device

This device is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

3.0 Predicate Comparison

The Electro-Gel has the same technological characteristics as the predicate devices. It is the conductor between the scalp and electrodes and reduces impedance between the electrode and the scalp.

(Please refer to the comparison tables on the following four pages).

Table 1 compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates (Prior July 2008) and TEN20 Conductive Paste.

Table 1: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	ELECTRO-GEL Prior July 2008	TEN20 Conductive Paste	Substantial Equivalence Comments
510K No.	K111717	K780045	K883149	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with non-disposable neurodiagnostic electrodes during EEG exams, EP procedures, ENG exams, brainmapping andMSLT procedures	Electro-Gel is used in the same environments and is substantially equivalent to the predicates.
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments as predicates.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Tragacanth, Glycerine	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL*	No OSHA PEL*	No OSHA PEL*	Same as predicates
Preservative	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Same as predicates

Biocompatibility	Test in accordance with ISO 10993		Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	No	Yes	Same as predicates
Irritation	Yes	No	Yes	Same as predicates
Sensitization	Yes	No	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic Excessive exposure to fingers may become chapped and dry	Equivalent to predicates

4.1 Comparison Summary

As shown above in Table 4.0, the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Table 2. Compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates Mavidon Electrode Jelly and Compumedics Quik Gel.

Table 2: Comparison to Predicate Devices				
Feature	**ELECTRO-GEL After July 2008**	**MAVIDON ELECTRODE JELLY**	**QUIK GEL**	**Substantial Equivalence Comments**
510K No.	K111717	K003924	K033052	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	A thixotropic conductive gel for use with silver, gold or tin electrodes.	The Quik Gel is intended for use when a reduction of skin impedance would enhance a test result. It also helps the Quik Cap electrodes adhere to the patient.	Electro-Gel is used in the same environments and is substantially equivalent to the predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Hydroxyethyl Cellulose	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL	No OSHA PEL	No OSHA PEL	Same as predicates
Preservative	Methylparaben and Propylparaben	Phenol	Anti-fungal Agents	Similar to predicates

Biocompatibility	Test in accordance with ISO 10993	Yes	Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	Yes	Yes	Same as predicates
Irritation	Yes	Yes	Yes	Same as predicates
Sensitization	Yes	Yes	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Same as predicates

4.1 Comparison Summary

As shown above in Table 4.0 Add., the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

4.0 Device Testing

The Electro-Gel has been tested by Toxikon Corporation, FDA/USDA Registered, in compliance with 21CFR, Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies, for the following test: Agar Diffusion Test, ISO 10993-5,-12, Primary Skin Irritation Test-ISO Direct Contact, ISO 10993-10,- 12 and Buehler Sensitization Test, ISO 10993-10, - 12. The Electro-Gel passed all tests.

Electro-Gel is tested internally for pH, impedance and viscosity on a regular basis.

4.0 Conclusions

Based on the results of the non-clinical tests (that demonstrate that the device is as safe, as effective and performs as well as the other legal marketed devices) we conclude that the intended use and technology of the Electro-Gel is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 5 2012

Electro-Cap International, Inc.
c/o Ms. Amy Swallows
Director of Marketing
1011 West Lexington Road
Eaton, OH 45320

Re: K111717
Trade/Device Name: Electro-Gel
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: December 19, 2011
Received: December 20, 2011

Dear Ms. Swallows:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B

Indications for Use

510(k) Number (if known): K111717

Device Name: Electro-Gel

Indications for Use:

Electro-Gel is intended for use in clinical and research EEG/EP recordings from humans. It is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

John Grimes

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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